



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Submission for OMB Review; 30-Day Comment Request; Assurance**

#### **(Interinstitutional, Foreign, and Domestic) and Annual Report Office of the Director (OD)**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To submit comments in writing or request more information on the proposed collection, contact: Jane J. Na, Director, Division of Assurances, Office of Laboratory Animal Welfare, NIH, call (301) 496-7163 or email your request to [olawdoa@mail.nih.gov](mailto:olawdoa@mail.nih.gov). Formal requests for information collection forms must be requested via email to [olawdoa@mail.nih.gov](mailto:olawdoa@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** This proposed information collection was previously published in the Federal Register on December 15, 2022, Vol. 87, No. 240 page 76631-76632 (87 FR 76631) and allowed 60 days for public comment. No public

comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The Office of the Director (OD), National Institutes of Health (NIH), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number.

In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, NIH has submitted to OMB a request for review and approval of the information collection listed below.

Proposed Collection Title: Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report, OMB #0925-0765, expiration date 11/30/2022, Reinstatement with Change, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: The NIH Office of Laboratory Welfare (OLAW) is responsible for the implementation, general administration, and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) as codified in 42 CFR 52.8. The PHS Policy implements the Health Research Extension Act (HREA) of 1985 (Public Law 99-158 as codified in 42 U.S.C. 289d). The PHS Policy requires entities that conduct research involving vertebrate animals using PHS funds to have an Institutional Animal Care and Use Committee (IACUC), provide assurance that requirements of the Policy are met, and submit an annual report. Institutions in foreign countries comply with the PHS Policy or provide evidence that acceptable standards for the humane care and use of the animals in PHS-conducted or -supported activities will be met. An institution's animal care and use program is described in the Animal Welfare Assurance (Assurance) document and sets forth institutional compliance with PHS Policy. The purpose of the Assurance

(Interinstitutional, Foreign, and Domestic) and Annual Report is to provide OLAW with documentation to satisfy the requirements of the HREA, illustrate institutional adherence to PHS Policy, and enable OLAW to carry out its mission to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 9,219.

#### Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Domestic Assurance	Renewal and New	235	1	30	7,050
Domestic Annual Report	All Domestic	890	1	90/60	1,335
Foreign Assurance	Renewal and New	67	1	90/60	101
Foreign Annual Report	All Foreign	335	1	1	335

Interinstitutional Assurance for Foreign Performance Site or Interinstitutional Assurance Triad for Foreign Performance Site	Foreign	46	1	30/60	23
Interinstitutional Assurance for Domestic Performance Site or Interinstitutional Assurance Triad for Domestic Performance Site	Domestic	750	1	30/60	375
TOTAL		2,323	6		9,219

Dated: November 22, 2023.

**Lawrence A. Tabak,**

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